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PATTON BOGGS LLP 8484 WESTPARK DRIVE SUITE 900 MCLEAN, VA 22102			EXAMINER SCHNIZER, RICHARD A	
			ART UNIT	PAPER NUMBER
			1635	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		01/12/2007	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

# Office Action Summary

Application No.

10/821,710

Applicant(s)

GRAHAM ET AL.

Examiner

Richard Schnizer, Ph. D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 20 November 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 44 and 77-141 is/are pending in the application.
- 4a) Of the above claim(s) 114-144 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 44,77-100 and 102-113 is/are rejected.
- 7) ☒ Claim(s) 101 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☒ Certified copies of the priority documents have been received in Application No. 09/646,807.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

An amendment was received and entered on 11/20/06

Claims 1-43, 45, 46, 49-55, and 62-76 have been canceled by amendments over the course of prosecution.

Claims 47, 48, and 56-61 were canceled and new claims 77-141 were added as requested.

Claims 44 and 77-141 are pending.

Newly submitted claims 114-144 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Invention 1, claims 44 and 77-113, is directed to an isolated nucleic acid molecule comprising a first RNA sequence of greater than 20 consecutive nucleotides which is identical in sequence to a region of a transcript of a target gene in a eukaryotic cell, and a second RNA sequence that is complementary to the first RNA sequence, wherein the first and second sequences are in the same strand and are separated by a stuffer fragment comprising a sequence of nucleotides, classified in class 536, subclass 24.5. Invention 2, claims 114-144 is directed to a eukaryotic cell comprising a non-endogenous nucleic acid molecule cells comprising a first RNA sequence of greater than 20 consecutive nucleotides which is identical in sequence to a region of a transcript of a target gene in a eukaryotic cell, and a second RNA sequence that is complementary to the first RNA sequence, wherein the first and second sequences are in the same strand and are separated by a stuffer fragment comprising a sequence of nucleotides, classified in class 424, subclass 93.2.

Inventions 1 and 2 are related because invention 2 requires the nucleic acid of invention 1. The inventions are distinct because invention 1 does not require the cell of invention 2, and further because invention 2 requires the presence of cells, it also requires search and examination that are non-coextensive with that required for invention 1, therefore restriction is proper.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 114-144 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03. At such time as allowable subject matter is identified for invention 1, the Examiner will consider rejoinder of claims from Invention 2 that require a nucleic acid commensurate in scope with that of invention 1.

Claims 44 and 77-113 are under consideration in this Office Action.

### ***Priority***

Applicant indicates at pages 14 and 15 of the response that instant claim 44, as amended on 11/20/06, finds support in Australian Patent application PP2429. However, the instant application does not claim priority to PP2429, and a review of the two Australian Applications to which priority is claimed (PP2492 and PP2499) revealed no support for a first ribonucleotide sequence of greater than 20 consecutive nucleotides that is identical in sequence to a region of a transcript of any target gene in a eukaryotic cell, as recited in instant claim 44. Support for independent claim 44 as amended on

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11/20/06 can be found in PCT/AU99/00195, filed 3/19/99. Thus the instant claims cannot have an effective filing date earlier than 3/19/99.

### ***Oath/Declaration***

Due to amendments to the claims removing matter not present in priority documents, the oath or declaration is no longer considered to be defective.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

### ***New Matter***

Claim 103 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 44 requires an isolated nucleic acid molecule comprising a first RNA sequence of greater than 20 consecutive nucleotides which is identical in sequence to a region of a transcript of a target gene, and a second RNA sequence that is complementary to the first RNA sequence wherein the first and second sequences are in the same strand and are separated by a stuffer fragment.

Claim 103 depends from claim 44 and further limits claim 44 by requiring that the stuffer fragment comprises an intron. Applicant asserts that the specification as filed supports this claim at page 15, line 30 to page 16 line 8. However, while this passage supports nucleic acid molecules in which an intron comprises a stuffer fragment, it fails to support a stuffer fragment that comprises a complete intron including splice sites within the stuffer fragment, as is embraced by the claim. Accordingly the claim recites new matter.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 44, 77, 80-87, 90, 91, 97, 98, 104-106, 110, 111, 114, 118, 119, 125-127, 129?, 130, and 131 are rejected under 35 U.S.C. 102(b) as being anticipated by Agrawal et al (WO 94/01550, of record).

Agrawal taught self-stabilizing RNA molecules comprising a region that is complementary to a target in a eukaryotic mRNA in a human cell and a region that is self-complementary. See abstract; page 8, lines 7-11 and 22-24, paragraph bridging pages 11 and 12, and page 13, lines 25-30. The target hybridizing region is from 8 to 50 nucleotides in length (sentence bridging pages 9 and 10). The self complementary regions may be separated by an unpaired nucleotide loop structure (see e.g. Fig. 1, and

page 15, lines 9-16). The target gene may be a viral gene. Disclosed viruses include human immunodeficiency virus, Yellow Fever virus (a single strand (+) RNA virus), and Herpes simplex virus (a double stranded DNA virus. See paragraph bridging pages 10 and 11. The target may be a member of a multi-gene family such as ras. See page 12, line 10. The oligonucleotide may be in a pharmaceutically acceptable carrier. See claim 18.

### ***Response to Arguments***

Applicant's arguments filed 11/20/06 have been fully considered but they are not persuasive.

Applicant argues at page 18 of the response that Agrawal does not teach connection of sense and antisense regions by a nucleic acid linker, as required by the instant claims. This is unpersuasive because Agrawal taught at page 15, lines 9-16 that the sense and antisense portions can be separated by non-base-paired nucleotides forming a loop. Accordingly the rejection is proper.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 102 is rejected under 35 U.S.C. 103(a) as being unpatentable over Agrawal et al (WO 94/01550, of record).

Agrawal taught self-stabilizing RNA molecules comprising a region that is complementary to a target in a eukaryotic mRNA in a human cell and a region that is self-complementary. See abstract; page 8, lines 7-11 and 22-24, paragraph bridging pages 11 and 12, and page 13, lines 25-30. The target hybridizing region is from 8 to 50 nucleotides in length (sentence bridging pages 9 and 10). The self complementary regions may be separated by an unpaired loop structure (see e.g. Fig. 1, and page 15, lines 9-16). Agrawal exemplified a loop structure of 4 nucleotides.

Agrawal did not teach a loop of 10-50 nucleotides.

Absent evidence of unexpected results, it would have been obvious to one of ordinary skill in the art to vary the length of the unpaired loop sequence of the self-stabilizing RNA of Agrawal in order to optimize hybridization of the complementary section of the oligonucleotides, thereby providing increased stability against nucleolytic attack.

Claims 44, 78, 79, 88, 89, and 112, and 113 are rejected under 35 U.S.C. 103(a) as being unpatentable over Agrawal et al (WO 94/01550, of record) in view of Day et al (Proc. Nat Acad. Sci. USA 88: 6721-6725, 1991).

Agrawal taught self-stabilizing RNA molecules comprising a region that is complementary to a target in a eukaryotic mRNA in a human cell and a region that is self-complementary. See abstract; page 8, lines 7-11 and 22-24, paragraph bridging



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pages 11 and 12, and page 13, lines 25-30. The target hybridizing region is from 8 to 50 nucleotides in length (sentence bridging pages 9 and 10). The self complementary regions may be separated by an unpaired loop structure (see e.g. Fig. 1, and page 15, lines 9-16).

Agrawal did not teach RNA molecules directed against a plant virus, nor an expression construct encoding the RNA molecules.

Day taught that transgenic plants comprising an expression construct encoding antisense RNA directed against a Gemini virus gene were resistant to the virus. See abstract.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the invention of Day by designing an expression construct encoding a self-stabilizing RNA molecule as taught by Agrawal. One would have been motivated to do so in order to increase the stability of the antisense RNA, thereby providing a reasonable expectation of improving viral resistance.

Claims 44, 88, 89, 99, 100, 112, and 113 are rejected under 35 U.S.C. 103(a) as being unpatentable over Agrawal et al (WO 94/01550, of record) in view of Shewmaker et al (US Patent 5,107,065).

Agrawal taught self-stabilizing RNA molecules comprising a region that is complementary to a target in a eukaryotic mRNA in a human cell and a region that is self-complementary. See abstract; page 8, lines 7-11 and 22-24, paragraph bridging pages 11 and 12, and page 13, lines 25-30. The target hybridizing region is from 8 to

50 nucleotides in length (sentence bridging pages 9 and 10). The self complementary regions may be separated by an unpaired loop structure (see e.g. Fig. 1, and page 15, lines 9-16).

Agrawal did not specifically teach an RNA with sequence identical to a region of a transcript in a plant cell, but noted that antisense regulation of gene expression in plant cells had been described, by Shewmaker, incorporating the teachings of Shewmaker by reference. Agrawal did not specify that the targeted region of the transcript was in the coding region or the 5'- or 3'-untranslated regions of the target. Agrawal did not teach an expression construct encoding the RNA molecules.

Shewmaker taught antisense regulation of gene expression in monocot or dicot plant cells by integrating into the genome of the plant cell a construct comprising in the 5'-3' direction of transcription a promoter functional in said plant cell, a dsDNA sequence wherein the transcribed strand of said dsDNA is complementary to RNA indigenous to said cell, whereby said complementary strand is transcribed and binds to said RNA indigenous to said cell, thereby inhibiting expression of said gene indigenous to said plant cell. See abstract, column 4, lines 1-3, and claims 6 and 7. The transcribed RNA can comprise sequence from either the 5' or 3' untranslated region. See e.g. claims 3 and 4. Alternatively the transcribed RNA can comprise sequence from all or part of the coding region. See column 2, lines 33-50.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the invention of Shewmaker by designing an expression construct encoding a self-stabilizing RNA molecule as taught by Agrawal. One would have been

motivated to do so in order to increase the stability of the antisense RNA, thereby providing a reasonable expectation of improving antisense performance.

Claims 44, 90, 92, and 94 are rejected under 35 U.S.C. 103(a) as being unpatentable over Agrawal et al (WO 94/01550, of record) in view of McGarry et al (Proc Nat. Acad. Sci. USA 83:399-403, 1986).

Agrawal taught self-stabilizing RNA molecules comprising a region that is complementary to a target in a eukaryotic mRNA in a human cell and a region that is self-complementary. See abstract; page 8, lines 7-11 and 22-24, paragraph bridging pages 11 and 12, and page 13, lines 25-30. The target hybridizing region is from 8 to 50 nucleotides in length (sentence bridging pages 9 and 10). The self complementary regions may be separated by an unpaired loop structure (see e.g. Fig. 1, and page 15, lines 9-16).

Agrawal did not teach RNA molecules directed against an RNA in a cell of an invertebrate animal or insect.

McGarry taught methods of inhibiting gene expression by expression of antisense RNA in cultured *Drosophila* cells.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the invention of McGarry by designing an expression construct encoding a self-stabilizing RNA molecule as taught by Agrawal. One would have been motivated to do so in order to increase the stability of the antisense RNA, thereby providing a reasonable expectation of improving antisense performance.

Claims 44, 90, and 92 are rejected under 35 U.S.C. 103(a) as being unpatentable over Agrawal et al (WO 94/01550, of record) in view of Powell-Coffman et al (Dev. Biol. 178:472-483, 1996).

Agrawal taught self-stabilizing RNA molecules comprising a region that is complementary to a target in a eukaryotic mRNA in a human cell and a region that is self-complementary. See abstract; page 8, lines 7-11 and 22-24, paragraph bridging pages 11 and 12, and page 13, lines 25-30. The target hybridizing region is from 8 to 50 nucleotides in length (sentence bridging pages 9 and 10). The self complementary regions may be separated by an unpaired loop structure (see e.g. Fig. 1, and page 15, lines 9-16).

Agrawal did not teach RNA molecules directed against an RNA in a cell of an invertebrate animal.

Powell-Coffman taught a method of inhibiting gene expression in *C. elegans* by administration of antisense RNA directed against the *ama-1* gene. See abstract.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the invention of Powell-Coffman by designing and using self-stabilizing antisense RNA molecules as taught by Agrawal. One would have been motivated to do so in order to increase the stability of the antisense RNA, thereby providing a reasonable expectation of improving antisense performance.

Claims 44, 90, 93, and 95 are rejected under 35 U.S.C. 103(a) as being unpatentable over Agrawal et al (WO 94/01550, of record) in view of Barabino et al (Mech. Dev. 63: 133-143, 1997).

Agrawal taught self-stabilizing RNA molecules comprising a region that is complementary to a target in a eukaryotic mRNA in a human cell and a region that is self-complementary. See abstract; page 8, lines 7-11 and 22-24, paragraph bridging pages 11 and 12, and page 13, lines 25-30. The target hybridizing region is from 8 to 50 nucleotides in length (sentence bridging pages 9 and 10). The self complementary regions may be separated by an unpaired loop structure (see e.g. Fig. 1, and page 15, lines 9-16).

Agrawal did not teach RNA molecules directed against an RNA in a cell of an aquatic animal.

Barabino taught methods of suppressing Alx gene expression in zebrafish embryos by administration of antisense oligonucleotides. See abstract.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the invention of Barabino by designing and using self-stabilizing antisense RNA molecules as taught by Agrawal. One would have been motivated to do so in order to increase antisense performance.

Claims 44, 90, and 96 are rejected under 35 U.S.C. 103(a) as being unpatentable over Agrawal et al (WO 94/01550, of record) in view of Swamynathan et al (J. Virol. 71(4): 2873-2880, 1997).

Agrawal taught self-stabilizing RNA molecules comprising a region that is complementary to a target in a eukaryotic mRNA in a human cell and a region that is self-complementary. See abstract; page 8, lines 7-11 and 22-24, paragraph bridging pages 11 and 12, and page 13, lines 25-30. The target hybridizing region is from 8 to 50 nucleotides in length (sentence bridging pages 9 and 10). The self complementary regions may be separated by an unpaired loop structure (see e.g. Fig. 1, and page 15, lines 9-16).

Agrawal did not teach RNA molecules directed against an RNA in a cell of an avian animal.

Swamynathan taught a method of inhibiting expression of chicken YB-2 in avian fibroblasts by administration of antisense RNA directed against the ama-1 gene. See abstract.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the invention of Swamynathan by designing and using self-stabilizing antisense RNA molecules as taught by Agrawal. One would have been motivated to do so in order to increase antisense performance.

Claims 44 and 107 are rejected under 35 U.S.C. 103(a) as being unpatentable over Agrawal et al (WO 94/01550, of record) in view of Schreiber et al (US Patent 5,858,981).

Agrawal taught self-stabilizing RNA molecules comprising a region that is complementary to a target in a eukaryotic mRNA in a human cell and a region that is

self-complementary. See abstract; page 8, lines 7-11 and 22-24, paragraph bridging pages 11 and 12, and page 13, lines 25-30. The target hybridizing region is from 8 to 50 nucleotides in length (sentence bridging pages 9 and 10). The self complementary regions may be separated by an unpaired loop structure (see e.g. Fig. 1, and page 15, lines 9-16).

Agrawal did not teach a self-stabilizing RNA molecule encapsulated in a liposome.

Schreiber taught that delivery of oligonucleotides was improved by complexing with cationic liposomes. This improvement was also observed when stem-loop oligonucleotides were used. See column 10, lines 47-54.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the invention of Agrawal by delivering the oligonucleotides encapsulated in liposomes as taught by Schreiber. One would have been motivated to do so to obtain improved delivery.

Claims 44, 108, and 109 are rejected under 35 U.S.C. 103(a) as being unpatentable over Agrawal et al (WO 94/01550, of record) in view of Dhalla et al (Bichem. J. 336(2): 373-379, 1998).

Agrawal taught self-stabilizing RNA molecules comprising a region that is complementary to a target in a eukaryotic mRNA in a human cell and a region that is self-complementary. See abstract; page 8, lines 7-11 and 22-24, paragraph bridging pages 11 and 12, and page 13, lines 25-30. The target hybridizing region is from 8 to

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50 nucleotides in length (sentence bridging pages 9 and 10). The self complementary regions may be separated by an unpaired loop structure (see e.g. Fig. 1, and page 15, lines 9-16).

Agrawal did not teach an RNA molecule in a viral particle.

Dhalla taught antisense inhibition of chk YB-1b expression in chicken fibroblasts by administration of retroviruses encoding antisense oligonucleotides. See abstract.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the invention of Dhalla by designing a retroviral expression construct encoding a self-stabilizing RNA molecule as taught by Agrawal. One would have been motivated to do so in order to increase the stability of the antisense RNA, thereby providing a reasonable expectation of improving antisense performance.

### ***Conclusion***

No claim is allowed. Claim 101 is objected to because it depends from a rejected claim, but would be allowable if rewritten in independent form incorporating all of the limitations of the claim from which it depends.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the



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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 571-272-0762. The examiner can normally be reached Monday through Friday between the hours of 6:00 AM and 3:30 PM. The examiner is off on alternate Fridays, but is sometimes in the office anyway.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, J. Douglas Schultz, can be reached at (571) 272-0763. The official central fax number is 571-273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

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Richard Schnizer, Ph.D.  
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